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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/465,276	12/16/1999	SINA BAVARI	003/175/SAP	8690

7590

07/12/2002

U S ARMY MEDICAL RESEARCH AND
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EXAMINER

ZEMAN, ROBERT A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 07/12/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/465,276

Applicant(s)

BAVARI ET AL.

Examiner

Robert A Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1,3,4,6-13,18,20 and 22-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,5,14-17,19,21,27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

The amendment and response filed on 4-15-2002 is acknowledged. Claims 2, 5, 14-17, 21 and 27 have been amended. Claims 2, 5, 14-17, 19, 21 and 27-28 are currently under examination.

This application contains claims 1, 3-4, 6-13, 18, 20 and 22-26 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that he has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Claim Objections Withdrawn

The objection to claim 14 for containing an obvious grammatical error is withdrawn in light of the amendment thereto.

The objection to claims 15 and 16 for the improper use of articles is withdrawn in light of the amendment thereto.

Claim Rejections Withdrawn

The rejection of claims 2, 5, 15-17, 19, 21 and 27-28 under 35 U.S.C. 112, first paragraph, for failing to satisfy the deposit requirements is withdrawn in light of the amendment thereto and Applicant's declaration that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent.

The rejection of claims 15, 17, 21 and 27 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by reading, in part, on non-elected inventions is withdrawn in light of the amendment thereto.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "A monoclonal antibody" is withdrawn in light of the amendment thereto.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "ATCC PTA-969" is withdrawn in light of the amendment thereto.

The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "A continuous hybridoma cell line" is withdrawn in light of the amendment thereto.

The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "which cell line produces" is withdrawn in light of the amendment thereto.

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The rejection of claim 16 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the terms "biological" is withdrawn. Applicant's arguments have been fully considered and deemed persuasive. Said term is being interpreted as meaning "biological samples" such as cells, tissues or biological fluids as they exist in nature.

Claim Rejections Maintained

35 USC § 112

The rejection of claims 17 and 19 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for reasons of record.

Claim 19 is drawn to a pharmaceutical composition. The specification, however, is silent on how such a composition would be used and equally silent on the efficacy of said compositions. People of skill in the art require documented factual evidence that a benefit can be derived by the therapeutic application of a substance. The instant specification fails to provide evidence that the claimed pharmaceutical compositions would elicit any type of beneficial therapeutic response. Since no evidence has been provided that illustrates or even suggests that the claimed pharmaceutical compositions are capable of eliciting a beneficial therapeutic response, one of skill in the art would not be able to make and use the claimed invention.

Claim 17 is drawn to the therapeutic use pharmaceutical compositions comprising **monoclonal antibody 6B2-2**. To be a therapeutic composition, the composition must elicit beneficial response in a reasonable model system. The specification, as filed, does not set forth

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that the claimed composition provides any sort of therapeutic effect in any model system that can be extrapolated to humans or higher mammals (or in human themselves). The specification describes in detail how the claimed antibody was isolated and characterized but is silent on its therapeutic use. While the skill in the art of immunology is high, to date, prediction of a therapeutic benefit (effect) for any given composition is quite unpredictable. Given the lack of success in the art, the lack of working examples, and the unpredictability of the generation of a therapeutic effect, the specification, as filed, is not enabling for the **therapeutic** use of **monoclonal antibody 6B2-2**

Applicant argues:

1. The 6B2-2 was shown to protect mice from BoNT/A intoxication hence one of skill in the art would be able to make and use the claimed invention in a therapeutic context.

Applicant's arguments have been fully considered and deemed non-persuasive. Applicant is correct in his assertion that the Specification is enabling for the **prophylactic** use of the 6B2-2 monoclonal antibody. However, the specification provides no data regarding the efficacy of 6B2-2 when administered to a subject suffering from BoNT/A intoxication and Applicant has not provided any data demonstrating that there is a 1 to 1 correlation between the efficacy of a given compound as a prophylactic and its efficacy as a therapeutic agent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by reading, in part, on non-elected inventions is maintained for reasons of record. All claims must be limited to the monoclonal antibody 6B2-2 and its use.

The rejection of claim 16 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the terms "pharmaceutical" is maintained for reasons of record. Applicant failed to address this rejection in his response.

New Grounds of Rejection

35 USC § 112

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The clean copy of the amended claim does not correspond to the marked-up copy. Specifically, in (1) the word "having" is omitted.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 2, 5, 14-17, 19, 21, and 27-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Bayari et al. (Vaccine, November 1998, Vol. 16 No. 19 pages 1850-1856).

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Bavari et al. disclose the monoclonal antibody 6B2-2 (see Table 2), methods for detecting BoNT/A utilizing said antibody and methods of capturing BoNT/A from a sample (see Methods section on page 1851).

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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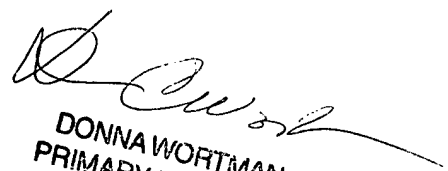
The above references were cited to indicate the methodologies employed to treat/prevent botulism intoxication.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donna Wortman can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman
July 11, 2002